UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875**
THIS DOCUMENT RELATES TO ALL CASES	**HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO COMPEL PRODUCTION OF TESTING AND OTHER MATERIALS IN THE POSSESSION OF CLASS EXPERT, DR. RON NAJAFI

PRELIMINARY STATEMENT

Defendants seek post-deposition discovery from one of Plaintiffs' class certification experts as to a merits question that has already been conclusively answered. In doing so, they provide a truncated, misleading gloss on the relevant facts, in an effort to create the impression that there is an issue of importance meriting the Court's intervention. When the relevant facts are accurately presented, it is apparent that Defendants seek extensive post-deposition discovery on a non-issue, despite assurances from and the offer of Plaintiffs to provide the central information sought on this motion.

Dr. Ron Najafi is an organic chemist and the owner of Emery Pharma ("Emery"), a contract research laboratory located in Alameda, California. Dr. Najafi was retained by Plaintiffs and to date has been put forward only on a single narrow issue as part of the class certification process. Specifically, Dr. Najafi opined: "Generic drug manufacturers have an ongoing federal duty of sameness in their products. The generic manufacturer must demonstrate that their ingredient(s)

are the same as the Reference Listed Drug ("RLD") and have identical strength, quality, purity, potency (and where applicable, other characteristics) as the RLD" and that "Valsartan containing products with NDMA and NDEA were not the same as or chemically equivalent to the brand name Diovan or Exforge products because they contained NDMA and NDEA." (ECF 1748-3, Dr. Najafi 11/1/21 Expert Declaration at 4, 7). Defendants now combine selective citations from Dr. Najafi's deposition and a mischaracterization of the extensive meet and confer between the parties on this subject in an effort to create the impression that there is an issue as to a fundamental settled fact – that the approved brand name Referenced Listed Drugs manufactured by Novartis, Diovan and Exforge, did not contain NDMA or NDEA.

The controlling facts are quite straightforward. On June 13, 2019 an independent testing laboratory named Valisure, which is NOT retained by or working with the Plaintiffs in this litigation, filed a citizen petition with the FDA identifying what it stated to be unsafe levels of two substances, N,N-Dimethylformamide ("DMF") and NDMA in various manufacturers' valsartan. The petition was submitted after most generic valsartan was removed from the market due to NDMA and NDEA contaminants, therefore the petition focused primarily on the solvent DMF. (*See* ECF 1984-1, Valisure Valsartan Cit. Pet. at 3).

Defendants incorrectly claim that Dr. Najafi testified that he had "[one] hundred percent certainty" Emery conducted testing in connection with Valisure's citizen petition submitted to the FDA on June 13, 2019. (ECF 2013-1, Defs.' Br. at 3). Dr. Najafi only agreed that he did testing at the request of Valisure, potentially before the FDA was even involved (first FDA recall of valsartan was in July of 2018). (ECF 2013-3, Najafi 2/3/22 Dep. Tr. 141:11-142:2). Dr. Najafi absolutely did not testify with "[o]ne hundred percent certainty" that Emery validated the testing

performed by Valisure *in connection with the citizen petition*. Defendants fail to note Dr. Najafi's testimony earlier in his deposition regarding Valisure's citizen petition:

> Q: And you said Valisure was making a lot of noise about valsartan, but have you ever seen a citizens petition from them?
>
> A: I don't recall.
>
> Q: With regard to valsartan?
>
> A: My memory is failing. I think – I don't think valsartan – I mean, you guys can google it, *whether Valisure filed any citizen petition on valsartan. I don't think so*. I think they just made a lot of press release, but I think the valsartan was removed from the market primarily due to Novartis finding genotoxic compound NDMA in valsartan from GMP and then effectively FDA was alerted. I think that's how the things kind of – how sort of everything fell into the, you know, basically the recall.

(Najafi 2/3/22 Dep. Tr. 124:7-124:22). Furthermore, Dr. Najafi testified that because Emery was not mentioned in the Valisure petition, it was his understanding that the results published in Valisure's petition had not been corroborated by Emery – thus he did not test those samples.[1] (Najafi 2/3/22 Dep Tr. 145:16-146:7, 148:6-148:21, 223:11-223:22).

Dr. Najafi has since verified that contemporaneous to Valisure's valsartan citizen petition, Emery tested a few valsartan pills for the presence of DMF and NDMA in a blinded manner (meaning that he was not told the manufacturers of the samples, which were labeled by sample number with no indication of the manufacturer when sent to him) for Valisure, so that Valisure could compare some of their internal testing to Emery's results. (Ron Najafi 4/25/2022 Declaration, Ex. B). Because Emery conducted the testing in a blinded manner, Emery was not and still is not aware of which manufacturer's pills it was testing. (*Id*.).

[1] In contrast, Valisure's citizen petition on Metformin explicitly states that Valisure sent Emery Pharma the same batch of Metformin to test that Valisure tested. (Valisure's Metformin Cit. Pet. at 8, 11, Ex. A).

ARGUMENT

As the Court and Defendants well know, Novartis did sell generic valsartan in Europe. In fact, it was a European arm of Novartis that purchased valsartan API from ZHP that led to the discovery of the NDMA when Novartis tested the API and identified the NDMA. (ZHP00007221 at 223, Ex. C). And Valisure's citizen petition refers to the Novartis pills by their generic names—valsartan and valsartan-HCTZ, and not by their brand names—Diovan and Exforge. (Valisure Valsartan Cit. Pet. at 9, 12; Najafi 2/3/22 Dep. Tr. 223:23-224:14). Moreover, this "issue" is really a red herring. It is ultimately irrelevant if it was Novartis generic or name brand valsartan that Valisure tested, because nitrosamines are not inherent to valsartan when properly manufactured, and Novartis' approved process does NOT utilize chemicals that pose a risk of nitrosamine formation, which was corroborated by ZHP. (ZHP00007221 at 225, 227, 229, 233, 237, 244; PRINSTON0075797 at 807-811, 879, 958, 964, 970, 022-024, 031-033, Ex. D). The approved form of the RLD does not include NDMA or NDEA. Moreover, valsartan-containing drugs ("VCDs") can be manufactured without the presence of mutagenic nitrosamines,[2] therefore the presence of nitrosamines in any VCD are unacceptable and indicates a cGMP deficiency.[3] (Najafi 2/3/22 Dep. Tr. 225:11-228:2; Clevenger 3/18/22 Dep. Tr. 78:3-83:13, Ex. F; John Quick 11/12/21 Expert Declaration at 7, 20-26, ECF 1748-4; Hecht Expert Report at 18, 23-26, ECF 1714-3). Even hypothetically giving the Defendants every benefit of the doubt and assuming that Valisure

[2] After the valsartan nitrosamine contamination became publicly known, the FDA issued an advice letter stating "[d]ue to their known potent carcinogenic effects, and **because it is *feasible* to limit these impurities by taking *responsible* steps to *prevent or eliminate their presence***, FDA has determined that there is no acceptable specification for nitrosamines in ARB API and DP." (ECF 1794-14, FDA General Advice Letter).

[3] On the USP webpage for nitrosamine impurities in ARBs, USP states that "[c]ompanies are responsible for understanding their *manufacturing processes*, which includes *identifying and preventing* the presence of *unacceptable impurities*." (https://www.usp.org/chemical-medicines/nitrosamine-impurities, Ex. E).

actually tested Novartis Diovan and Exforge (as set forth below that is not an assumption with any real foundation), the presence of NDMA in Diovan and Exforge would only indicate that Novartis was experiencing cGMP problems – which is quite unlikely to have first been discovered at this late date. To place this in more focus, if Novartis' manufacturing practices were to deteriorate next month, resulting in Novartis manufacturing and selling Diovan or Exforge with more than 96 ng of NDMA, then Novartis would also be selling adulterated drugs, but that wouldn't alleviate or lessen the culpability of the generic manufacturer Defendants that sold adulterated valsartan for years.

In fact, even if Defendants' greatest hope were borne out and the Novartis valsartan was Diovan, the likelihood is that the NDMA detected was due to a testing issue and not because the Novartis pills actually contained NDMA. In this context, the amount of NDMA Valisure reported in Novartis' valsartan did not scale at all with the milligrams of the pill, which has been generally observed for all of the Defendants' contaminated VCDs. (Valisure Valsartan Cit. Pet. at 9, 12). Instead, the amounts of NDMA allegedly detected by Valisure in Novartis valsartan remained in the same range (not detected – 17 ng) for both 40 mg and 320 mg pills. (*Id*.). If Novartis' valsartan API was contaminated with NDMA, then it would be expected that the pills with 320 mg of valsartan API would have higher NDMA levels than pills with only 40 mg of valsartan API. Therefore, Valisure's testing results suggest that the source of the approximately 14 ng (average) of NDMA reported by Valisure in Novartis valsartan was the result of a testing error caused by residual NDMA in Valisure's gas chromatography machine after testing samples of pills (from other manufacturers) with NDMA present.

Valisure's results for Aurobindo's valsartan further confirm that at some point Valisure's gas chromatography machine likely became impacted by residual NDMA, causing it to return false

positives for NDMA in the single digit to low double digit nanogram levels. Aurobindo hired Exponent to review the levels of NDMA and NDEA that Aurobindo reportedly found in its VCDs. In the expert report submitted by Dr. Jason Clevenger on behalf of Exponent, it was specifically called out that, "It should be noted that according to the data provided by Aurobindo, no detectable levels of NDMA were found in any batch of finished drug product." (Exponent/Dr. Clevenger Expert Report at 12, Ex. G). In deposition, Dr. Clevenger repeatedly testified that the data provided by Aurobindo was "the most comprehensive dataset that was available at that time". (Clevenger 3/18/22 Dep. Tr. 213:11-:25, 31:22-23, 179:7-18, 180:5-18, 181:9-16). However, Valisure reported NDMA ranging from 6-28 ng (12.7 ng average) in 21 out of 36 Aurobindo pills tested. (Valisure Valsartan Cit. Pet. at 11-12). Additionally, the levels of NDMA that Valisure reported in Aurobindo's valsartan did not scale at all with the milligrams of the pill as would be expected. (*Id*.). Thus, it is likely that Valisure's testing method was impacted by residual NDMA in the gas chromatography machine, or there is another testing anomaly at work.

Relative to the results reported by Aurobindo, Defendants argue that the other valsartan testing results reported by Valisure included generic valsartan sold by Defendants. (Defs.' Br. at 6-8, 10). However, the only other Defendant mentioned in the Valisure petition is Aurobindo, and as we know from discovery and as set forth above, Aurobindo's valsartan was almost always contaminated with NDEA, not NDMA. Neither Valisure nor Emery would have detected NDEA in Aurobindo's pills, because neither of them tested the pills for NDEA. (4/25/2022 Declaration of Ron Najafi; Valisure Valsartan Cit. Pet.; Najafi 2/3/22 Dep. Tr. 224:15-19).[4]

[4] Defense counsel incorrectly claimed in the CMC that Valisure reported NDEA levels. (3/30/2022 CMC at 5:10-6:1, Ex. H).

Unlike Valisure, Health Canada (department of the Government of Canada responsible for national health) specifically listed Diovan as the Novartis pill it tested. (Health Canada at 9, Ex. I). As expected, Health Canada did not find any detectable level of NDMA in Novartis' name brand valsartan.[5] (*Id.*; Najafi 2/3/22 Dep. Tr. 219:12-222:21). Health Canada further provided their testing method was "developed to detect and quantify the nitrosamine impurities N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA) in angiotensin II receptor blockers (ARBs)." (Health Canada at 11). Additionally, no regulatory agency in the world has raised any issue regarding nitrosamines in Diovan or Exforge. The FDA's list of Recalled Angiotensin II Receptors (ARBs) does not list any Novartis products, while Novartis' Diovan, Diovan HCT, Entestro, Exforge, and Exforge HCT all appear on the FDA's list of valsartan products not currently recalled. (FDA ARB Recall List, Ex. J; FDA Valsartan Not Recalled List, Ex. K). Thus, Defendants are seeking to overcome established test results by world authorities.

In other words, even if the Defendants were correct in their hopes that the samples tested by Valisure and reported to the FDA which contained DMF and NDMA were Diovan, that would be inconsistent with the testing reported worldwide, and likely due to something inherent in Valisure's process, for example cross-contamination caused by and unique to Valisure's process. This would prove nothing of import here. If Diovan contained NDMA, the Defendants surely would know this from their own testing[6] and they would have advanced that evidence to the FDA and other regulatory authorities when they were facing massive regulatory actions and initiating

[5] Health Canada's testing method was capable of detecting NDMA at single nanogram levels.

[6] Multiple Defendants have contacted Exponent for their services in this litigation, yet Dr. Clevenger refused to disclose which Defendants have retained Exponent, if Exponent has conducted pill testing for any Defendants, or how much money Exponent has made off of this litigation. Defendants have not offered such information when their expert was asked for it and Plaintiffs reserve their rights pending the outcome here. (Clevenger 3/18/22 Dep. Tr. 16:9-21:10, 48:22-50:21, 52:19-53:24).

recalls in 2018. Therefore, whatever Valisure did, it impacts no important facts or assumptions in this litigation.

Against this backdrop, Defendants' requests are overreaching to say the least. Defendants' initial request to Plaintiffs demanded the production of extensive information, including the "results of all testing performed by Emery Pharma and/or Valisure on any valsartan drug substance or drug product" and Emery protocols. (ECF 1984-2, Defs.' 2/16/22 Letter to PEC). Valisure has not been retained by Plaintiffs in this litigation and has not performed any work for Plaintiffs in this litigation. Whatever that non-regulatory entity did or says is not chargeable to the Plaintiffs here, nor should discovery on that front be permitted at this stage where the petition was public in 2019.

The parties engaged in a meet and confer process after receiving Defendants' requests. During that back-and-forth, Plaintiffs answered the Defendants' inquiries and the issues were substantially narrowed. The remaining question from Defendants was described by defense counsel during the March 30, 2022 conference with the Court. Defense counsel explained to the Court that Defendants were focused on attempting to establish that the Valisure petition, which indicated the presence of DMF and NDMA in "Novartis valsartan" tested by Valisure actually proved that the brand name Diovan and Exforge contained NDMA. Despite acknowledging that Plaintiffs had consulted with Dr. Najafi and confirmed during the meet and confer that the results of the testing by Emery did not match any of the Valisure reported results for the Novartis valsartan, Defendants were not content to believe Plaintiffs' counsel:

> We want the results of that testing and the data underlying that testing. We believe it will undermine his core opinion in this case, that equivalence requires a generic and branded product to have matching impurity profiles. There is no such requirement that exists, but Najafi suggests it does. And the testing from Valisure, as we demonstrated in his deposition, shows that Novartis's product contains

> NDEA in it. It was tested and shown to contain NDEA in it.[7] And if this expert, who is saying that any product that has any level of this nitrosamine impurity is misbranded and adulterated and is not equivalent to the brand, the fact is the brand product has it undermines his sworn testimony.
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> ****
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> Mr. Trischler: Sure, Your Honor. Thank you. When I listened to Mr. Slater's comments, I was harkened back to – I think it was President Reagan who was trying to negotiate a disarmament deal with the then Soviet Union. And I think, you know, he was talking about how do we go about doing that. And he said, *trust but verify*.
>
> And the plaintiffs' position on this issue is we're supposed to trust them, Judge, but they leave out the verification part, which is what discovery is all about. *We get to trust but verify*. So Mr. Slater is continuing to represent and has represented, and you heard him here this morning, that despite the sworn testimony from the witness, who on page 141 and 142, I'm looking at his transcript now, says that he tested – independently tested and verified the Valisure results which showed testing of Novartis product, despite all that, *they never tested Diovan. We should trust that.*
>
> Well, in discovery, though, Judge, *we get to verify that*. And *trust but verify. And that's what we're asking to do*. That's what the rules provide. I think we're entitled to it. Again, we're happy to meet and confer.

(3/30/22 CMC at 5:10-6:1, 10:15-11:10).

Accordingly, at the next meet and confer, Plaintiffs offered to attempt obtaining permission to disclose Emery's blinded test results to Defendants, so Defendants could compare Emery's blinded results to the data in the Valisure petition to confirm that they did not match one another, if that would put this issue to bed. Defendants expressed a vague concern that if the results were not exact matches but very close, this could be within a "margin of error," and thus the lack of an exact match would not be dispositive. Plaintiffs asked what margin of error Defendants believed to be reasonable, but Defendants were unable to provide any position on this point. Plaintiffs were willing to obtain permission to provide the information that defense counsel focused on during the case management conference, as long as there was a clear understanding that if Emery's testing results demonstrated that they did not match Valisure's Novartis valsartan numbers, taking into account an agreed margin of error, this would end the inquiry. Defense counsel agreed to get back

[7] Valisure did not test for NDEA. (Valisure Valsartan Cit. Pet.).

with Plaintiffs, but instead ceased any further discussion on the topic with Plaintiffs and filed their motion, which significantly expanded the inquiry beyond the narrow issue presented to the Court and Plaintiffs following the narrowing meet and confer process.

CONCLUSION

Defendants' motion is nothing more than a fishing expedition intended to distract, and delay class certification. Defendants' request is no longer limited to the ability to compare Emery's test results to the results in Valisure's petition, with the focus on Novartis' valsartan, as represented at the case management conference. Instead, Defendants now attempt to also obtain protocols and other irrelevant and burdensome information. This expanded demand is advanced as if the meet and confer process did not occur. This flies in the face of the purpose of the meet and confer process, which worked here to pinpoint what the Defendants were truly focused on and should not be brushed aside, which would devalue the entire point of the work that was put into that process. Defendants' request is overbroad and irrelevant to any issue related to class certification.

Defendants' request for wide ranging post-deposition discovery from a class certification expert on the merits – during the class certification phase – while ignoring a good faith proffer and offer by Plaintiffs that could have avoided the need for this motion, should be denied. At this phase, where the only question is whether the class claims are amenable to treatment on a class basis, there is no basis to trigger the discovery requested by Defendants, which goes far beyond the information that defense counsel represented to be at issue when addressing the Court. Plaintiffs therefore request that the requested post-deposition discovery of Dr. Najafi be denied.

In the alternative, in the event the Court believes that some information should be evaluated, this should be done in a measured way, taking into account the confidentiality under which Emery performed its work at Valisure's request. At most, the Emery test results should be

submitted in camera to the Special Master, and the Special Master can confirm whether or not Plaintiffs are correct that Emery's results are not similar to the Novartis valsartan results submitted by Valisure. Since Emery only tested a limited number of samples on a confidential basis for Valisure, in camera review will not be burdensome to the Court and would provide the Court with the information that was pinpointed by defense counsel as being the heart of the matter. Assuming that the Special Master is satisfied that there is not overlap, this can be confirmed in an Order and the matter can be closed. If the Special Master determines that there is any overlap, those results that are the same, or even close (none are close to the Novartis valsartan this application is actually focused on), only those results would potentially be produced to the Defendants. And as stated above, since those samples were prepared by Valisure, a non-party and non-expert in this litigation, even if there was overlap, that information would be of no import in this litigation. In either case, this issue can be closed.

Dated: April 25, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of April 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ C. Brett Vaughn
C. Brett Vaughn